



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-E-0139]

Determination of Regulatory Review Period for Purposes of Patent Extension; EQUIDONE GEL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EQUIDONE GEL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman,  
Office of Regulatory Policy,  
Food and Drug Administration,  
10903 New Hampshire Ave.,  
Bldg. 51, rm. 6284,

Silver Spring, MD 20993-0002,  
301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA approved for marketing the animal drug product EQUIDONE GEL (domperidone). EQUIDONE GEL is indicated for prevention of fescue toxicosis in periparturient mares.

Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EQUIDONE GEL (U.S. Patent No. 5,372,818) from Dechra, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2011, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of EQUIDONE GEL represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EQUIDONE GEL is 6,378 days. Of this time, 6,336 days occurred during the testing phase of the regulatory review period, while 42 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective: March 26, 1993. The applicant claims February 24, 1992, as the date the investigational new animal drug application (IND) became effective. However, the date that a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption (NCIE) for a new animal drug, whichever is earlier, is the effective date for the IND. According to FDA records, the applicant's first submission of an NCIE was March 26, 1993, which is the effective date for the IND.
2. The date the application was initially submitted with respect to the animal drug product under section 512 of the Federal Food, Drug, and Cosmetic Act: July 30, 2010. The applicant claims July 27, 2010, as the date the new animal drug application (NADA) for

EQUIDONE GEL (NADA 141-314) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-314 was July 30, 2010, which is considered to be the initially submitted date for NADA 141-314.

3. The date the application was approved: September 9, 2010. FDA has verified the applicant's claim that NADA 141-314 was approved on September 9, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) either written or electronic comments and ask for a redetermination by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 31, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on

<http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,  
Associate Director for Policy,  
Center for Drug Evaluation and Research.

[FR Doc. 2012-10853 Filed 05/03/2012 at 8:45 am; Publication Date: 05/04/2012]